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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,857

05/11/2005

Ross E. Mantle

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EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

06/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,857

Applicant(s)

MANTLE, ROSS E.

Examiner

Phil Wiest

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 May 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/11/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I: Claims 1-13 in the reply filed on 2/16/07 is acknowledged.

ClaimS 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/16/07.

Drawings

2. The informal drawings are not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Applicant is given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1-9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (US 4,450,841) in view of Leonard (US 3,927,980), and further in view of Ginsburg et al. (US 6,497,721).
5. With respect to Claim 1, Osterholm discloses an apparatus for modulating the temperature and pressure within a body cavity by means of recirculating of a biologically compatible liquid, the apparatus comprising a first pump means 18 for infusing liquid at a controlled temperature and flow rate into the cavity, means for monitoring temperature of fluid (14, 40), and means for monitoring pressure of the fluid (18, 38). Osterholm, however, does not disclose that the monitoring means monitor temperature and pressure within the cavity, nor does it teach a second pumping means for withdrawing liquid at a controlled rate from the cavity.

6. Regarding Osterholm's lack of a second pumping means, Leonard discloses an extracorporeal system comprising a first pump 36 capable of infusing a liquid and a second pump 40 capable of withdrawing a liquid at a controlled flow rate (see Figure 1). The use of a plurality of pumps and a liquid storage means allows fluid to be withdrawn from the cavity at a different than it is infused, such that the pressure within the cavity can be controlled. When controlling the pressure within a cavity, is it obvious that pressure changes may be realized by changing the amount of fluid present within the cavity. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Osterholm with the plurality of pumps of Leonard so that the flow rate of fluid into and out of the cavity may be controlled, thereby regulating the pressure within the cavity.

7. Regarding Osterholm's lack of monitors within the cavity, Ginsburg et al. (hereafter "Ginsburg") discloses an apparatus for regional temperature modification wherein cranial pressure and temperature may be monitored and controlled (Column 5, Lines 58-65, Column 14, Lines 49-59, and Abstract). While Osterholm does disclose the monitoring of temperature and pressure, it is done so within the liquid storage chamber and not within the body. It is obvious that temperature measurements will be more accurate inside the body than in a fluid reservoir. Additionally, taking internal pressure measurements allows the pressure within the cavity to be controlled. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Osterholm with the use of internal pressure and temperature monitoring of Ginsburg in order to more accurately monitor the pressure and

temperature inside the cavity, thereby allowing the apparatus to change the flow rate and heat transfer settings accordingly.

8. With respect to Claim 6, Osterholm discloses a liquid storage means (10, 12, 14, 16, and 28) situated between the inflow and outflow catheters. The liquid storage means draws fluid from the outflow catheter, treats the fluid, and pumps the fluid back into the body cavity (see Figure 1).

9. With respect to Claim 7, Osterholm discloses a first catheter (connecting the spinal subarachnoid space 26 and the output collection 28) and a second catheter 30 to withdraw liquid from the cavity to the liquid storage means.

10. With respect to Claims 8 and 9, Osterholm discloses means to oxygenate and adjust the pH of the liquid (Column 14, Line 55 through Column 15, Line 21).

11. With respect to Claim 2, Osterholm in view of Leonard and Ginsburg discloses the apparatus of Claim 1; wherein fluid is circulated out of and back into the body through lumens connected to pumps (see the above rejection). Ginsburg further discloses the use of a dual-lumen catheter comprising an inflow lumen and an outflow lumen to circulate fluid into and out of a body region (see Figure 2). The use of dual-lumen catheters to circulate a liquid or introduce multiple fluids is established in the art because they allow a single incision to be made in the skin, thereby reducing the pain that a patient experiences. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Osterholm in view of Leonard and Ginsburg with Ginsburg's use of a dual lumen catheter because doing so would

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enable fluid to be circulated in and out of a body while reducing the number of incisions necessary from two to one.

12. With respect to Claims 3-5, Osterholm discloses a further catheter 30 connecting the cavity and the liquid storage means. The further catheter withdraws fluid from a different part of the brain such that treatment may be focused at specific areas of the cavity (Column 13, Lines 4-29). Osterholm, however, does not specifically disclose the use of a pump to withdraw fluid from the cavity through the further catheter. As explained above, Osterholm in view of Leonard and Ginsburg disclose an apparatus for circulating fluids in a body cavity comprising a pump to move fluid through the catheter and pressure and temperature monitoring means that control the pump. This configuration allows fluid to be drawn from the catheter at an optimal rate as determined by the sensors. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the further catheter of Osterholm with the catheter pumping and monitoring means of Osterholm in view of Leonard and Ginsburg in order to provide controlled flow from a second position within a body cavity such that treatment may be localized at specific points within the cavity.

13. With respect to Claims 11 and 12, Osterholm in view of Leonard and Ginsburg discloses the device of Claims 1 and 6, and that temperature and pressure sensors may be placed at the tip of a catheter such that they record the temperature and pressure inside a body cavity (see rejection above). The pumps may controlled in order to control the pressure inside the cavity (see Osterholm: Column 14, Lines 28-33).

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Furthermore, Ginsburg discloses that a pump is responsive to the difference between the temperature in the cavity (reference temperature) and the temperature in the liquid storage means (Column 22, Lines 36-47). Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the device of Osterholm in view of Leonard and Ginsburg with the temperature-based pump control of Ginsburg and the pressure-based pump control of Osterholm because doing so would allow both temperature and pressure to be controlled by altering the flow rate of fluid into and out of the cavity.

14. With respect to Claim 13, Osterholm discloses means 18 responsive to the pressure sensed pressure monitoring means 38. Osterholm, however, does not disclose that said pressure monitoring means are disposed within the cavity. As explained above, Ginsburg discloses a device wherein temperature and cranial pressure are monitored in order to control the system (Column 14, Lines 49-59). These internal pressure measurements allow the pressure in the system (i.e. speed of the pump) to be controlled such that pressure in the cavity reaches an optimal level. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Osterholm in view of Leonard and Ginsburg with the use of internal pressure and temperature monitoring of Ginsburg in order to more accurately monitor the pressure and temperature inside the cavity, thereby allowing the apparatus to change the flow rate and heat transfer settings accordingly.

15. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm in view of Leonard, and further in view of Ginsburg and Guitierrez-Collazo (US 5,562,821). Osterholm in view of Leonard and Ginsburg disclose the device of Claims 1 and 6 (see rejection above). Osterholm further discloses that the liquid is sterilized by sterilization unit 32 and harmful chemicals are removed by filter element 12 (see Figure 1) while in the liquid storage means, but does not specifically disclose contaminants are removed by foam fractionation. Guitierrez-Collazo discloses a foam fractionation device that removes contaminants from an aquatic environment by creating a vortex. This method of purification is well established in the art of fluid filtration as a method of removing organic compounds in order to prevent the build-up of bacterial byproducts, which could cause infection (Column 2, Lines 21-30). Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the device of Osterholm in view of Leonard and Ginsburg with the use of a foam fractionator of Guitierrez-Collazo in order to provide an alternate means for removing contaminants from the liquid before returning it to the body.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

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17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
6/21/07

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

